REMARKS

Claims 1-4, 14-19, 21, 22, 25-29 and 33-39 are now in the application. The recent personal interview so courteously granted the undersigned by Primary Examiner Peselev is hereby noted with appreciation. Claims 5-13 have been cancelled without prejudice to their reentry at some later date such as in a continuing application. Claims 1-4, 14-19, 21, 22, 25-29, 33, 34 and 35 are directed to the elected species. Claims 36-39 are directed to non-elected species.

Claim 1 has been amended to recite "at least one ion exchange resin." Claim 1 has also been amended to recite a ratio of the "at least one pharmaceutically active agent to the at least one ion exchange resin of about 3:1 to about 1:3."

Claims 1 and 14 have also been amended by reciting "adsorption" in place of "absorption" for purposes of clarification and not to restrict their scope. Claims 17 and 27 have been amended by deleting 3:1 to 1:3 in view of the amendment to claim 1.

The amendment to claim 1 reciting "at least one ion exchange resin" finds basis in the specification, for example, at page 3, line 18. The amendment to claim 1 reciting "at least one pharmaceutically active agent to the at least one ion exchange resin of about 3:1 to about 1:3" finds basis in the specification, for example, at page 17, line 15-16. Support for new claim 35 can be found, for instance, at page 4, line 14 and page 35, lines 7 and 8. Support for new claim 36 can be found, for instance, at page 4, line 17 and page 35, line11. Support for new claim 37 can be found, for instance at page 8, line 15. Support for new claim 38 can be found, for instance, at page 8, line 14. Support for new claim 39 can be found for instance on page 4, line 20 and page 35, lines 7 and 8. The amendments to the claims and newly presented claims 35-39 do not introduce any new matter.

As discussed at the interview, the rejection of claims 1-4, 7, 14-19, 21, 22, 25-29, 33 and 34 under 35 USC 103 as being obvious over U.S. Patent 5,980,882 to Eichman

in view of US Patent 6,596,298 to Leung, et al has been overcome by the filing of the attached Statement of Common Ownership. In view of the common ownership, the rejection under 35 USC 103(a) is not tenable pursuant to 35 USC 103(c).

Claims 1-4, 7, 14-19, 21, 22, 25-29, 33 and 34 were rejected under 35 USC 103 as being obvious over U.S. Patent 5,980,882 to Eichman in view of US Patent 5,411,945 to Ozaki, et al. Eichman and Ozaki, et al. fail to render obvious the above claims.

The above claims relate to an orally consumable solid film that comprises at least one water soluble polymer, an adsorption complex that comprises at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent or method of making. The film is adapted to adhere to and dissolve in the mouth of a consumer.

Eichman fails to suggest the present invention since, among other things, Eichman does not even remotely suggest that the complexes discussed therein could or should be used in orally-consumable solid films containing at least one water soluble resin.

Ozaki et al. was relied upon for a disclosure of the film-forming ability of pullulan. However, Ozaki et al. fails to suggest that films of pullulan could be used in conjunction with a complex of a pharmaceutically active agent and an ion exchange resin to obtain an orally-consumable solid film.

The cited art lacks the motivation for forming an orally consumable solid film of a water soluble resin and complex of a pharmaceutically active agent and an ion exchange resin. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention needed to sustain a rejection under 35 USC 103.

The combination and balance of different properties that would be desired from the type of product to which this invention is directed are quite difficult to achieve. For instance, along with masking the taste of the active agent, the limitations on the size or volume of the film place demands on being able to achieve sufficient dosage of the active agent. This is to be accomplished without the need for unduly increasing the volume or dimensions of the film so as not to lose the advantage of its convenience.

Furthermore, as discussed at the interview, it was not predictable that the presence of the ion exchange resin would be beneficial without adversely affecting the properties of the film such as damaging its integrity, or causing brittleness, grittiness or an other undesirable feel, or dehydrating the film to an undesired extent. In fact, as pointed out during the interview, attempts at coating the active agent and using the coated component in a film of a water soluble polymer, e.g. pullulan, resulted in a gritty and bitter product.

Along these lines, please see the comparative films in examples 1, 2 and 3 (Tables 1, 2 and 3) on pages 22-27 of the specification. On the other hand, films employing complexes of pharmaceutically active agents and ion exchange resins in accordance with the above claims exhibit desired appearance and taste characteristics. Please see examples 4-7 (Tables 4-7) on pages 27-32 of the specification.

Accordingly, the cited art fails to render obvious the above claims.

In view of the above, consideration and allowance are, therefore, respectfully solicited.

In the event that the Examiner believes that another interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication including any extension fees to Deposit Account No. 22-0185.

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Respectfully submitted,

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